# 510(k) Summary
# HemosIL Protein C

K062430

**Submitted by:**

Instrumentation Laboratory Company
113 Hartwell Avenue
Lexington, MA 02421

SEP - 1 2006

**Contact Person:**

Carol Marble, Regulatory Affairs Director
Phone No.: 781-861-4467
Fax No.: 781-861-4207

**Summary Prepared:**

August 18, 2006

**Name of the Device:**

HemosIL Protein C

**Regulatory Information:**

| | | |
|---|---|---|
| 864.7290 | Factor Deficiency Test | Class II |
| 81GGP | Test, Qualitative and Quantitative Factor Deficient | |

**Identification of Predicate Device(s):**

K980875 HemosIL Protein C

**Device Description:**

HemosIL Protein C is an *in vitro* diagnostic test for the quantitative determination of Protein C in human citrated plasma based on a synthetic chromogenic substrate. Protein C deficiency is associated with recurrent venous thrombosis, especially in young adults. Acquired deficiencies of Protein C are associated with hepatic disorders, oral anticoagulant therapy and disseminated intravascular coagulation.

**Reason for Submission:**

The Expected Values section of the HemosIL Protein C insert is being modified to reference a normal range from published literature, reinforcing the need for each laboratory to establish its own normal [reference] range due to the many variables which may affect results.

**Statement of Technological Characteristics of the Device Compared to Predicate Device:**

HemosIL Protein C with the modified Expected Values section in the product insert is not materially different from the FDA cleared device.

**Summary of Expected Values Section to the Modified Product Insert:**

Protein C activity levels in healthy individuals are approximately in the range of 70 – 140%. Protein C levels are low in neonates and infants and increase to adult levels during adolescence.*

Due to many variables which may affect results, each laboratory should establish its own normal range.

* Kottke-Marchant K, Comp P. Laboratory Issues in Diagnosing Abnormalities of Protein C, Thrombomodulin, and Endothelial Cell Protein C Receptor, Arch Pathol Lab med 2002; 126:1337-1348.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Carol Marble
Regulatory Affairs Director
Instrumentation Laboratory Co.
113 Hartwell Avenue
Lexington, MA 02421

SEP - 1 2006

Re: k062430
Trade/Device Name: HemosIL Protein C
Regulation Number: 21 CFR § 864.7290
Regulation Name: Factor Deficiency Test
Regulatory Class: II
Product Code: GGP
Dated: August 18, 2006
Received: August 21, 2006

Dear Ms. Marble:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Robert L. Becker, Jr., MD, Ph.D
Director
Division of Immunology and Hematology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

# Indications for Use Statement

**510(k) Number (if known):** K062430

**Device Name:** HemosIL Protein C

## Indications for Use:

HemosIL Protein C is an *in vitro* diagnostic test for the quantitative determination of Protein C in human citrated plasma based on a synthetic chromogenic substrate. Protein C deficiency is associated with recurrent venous thrombosis, especially in young adults. Acquired deficiencies of Protein C are associated with hepatic disorders, oral anticoagulant therapy and disseminated intravascular coagulation.

Prescription Use √ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

---

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K062430